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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,659	01/17/2007	Max Acbi	001227/0204	4698

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EXAMINER	
YANG, ANDREW	

ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,659	AEBI ET AL.	
	Examiner	Art Unit	
	Andrew Yang	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20 and 21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 19 and 20 of copending Application No. 10/538950. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (U.S. Patent No. 7273496) in view of Pisharodi (U.S. Patent No. 6610093).

Mitchell discloses an intervertebral implant 100 having a central axis, an upper section 110 and a lower section 120. The upper section 110 has a ventral side, a dorsal side, two lateral sides, a top apposition surface 112, and a bottom surface 116. The lower section 120 has a ventral side, a dorsal side, two lateral sides, a top apposition surface 122, and a bottom surface 126. The two sections 110, 120 are moveable with respect to each other (Column 3, Lines 27-30) via two joints arranged between the two sections. Each of the joints has a swivel axle and the two swivel axles are arranged perpendicular to each other as will be described herein. The two joints have an upper joint element 150 in the upper section 110, a central joint element 130, and a lower joint element 160 in the lower section 120. As seen in Figures 1D-1G, elements 150 and 160 define swivel axles that are perpendicular to each other. Each joint element also has at least one axle coaxial to the swivel axle and a second joint element with at least one bearing shell, which will be further described herein. The central joint element has one axle 220 that is coaxial to the swivel axle defined by element 160 wherein element 160 is a bearing shell for receiving the axle. With regards to claim 3, Mitchell discloses the central element having an axle 210 coaxial to the swivel axle as defined by element 150 and the upper joint element 150 having a bearing shell for receiving the axle 210. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Mitchell with the central element having the bearing

shell and the upper element having the axle, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Mitchell fails to disclose the implant having roll bodies between the axles and the bearing shells. More specifically, Mitchell fails to disclose the roll bodies being rotation symmetric bodies, and the bearing shells having grooves for receiving the roll bodies or the axles having grooves for the roll bodies, wherein the grooves in the cross-section area orthogonal to the swivel axle are arranged in a circular arc with a sector angle between 0 and 180 degrees. Pisharodi teaches an intervertebral implant 10 with an upper section 22 and a lower section 24 that are movable relative to each other via a joint. The joint consists of an axle 38 and a bearing shell 39. The bearing shell 39 has grooves with bearings 52 therein (Figure 3). The grooves in cross section area orthogonal to swivel axle are arranged in a circular arc with a sector angle between 0 and 180 degrees (Figure 3). With regards to claim 6, Pisharodi fails to discloses the axle having the groove with the bearings therein. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Pisharodi with the axle having the groove with bearings therein, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167. Furthermore, Pisharodi teaches the use of bearings 52 within the bearing shell 39, but more specifically the use of bearing between articulating surfaces in order to reduce friction and extend the life of the parts (Column 4, Lines 17-23). It would have been obvious to one skilled in the art at the time

the invention was made to construct the device of Mitchell with a groove in the bearing shell or the axle with bearings there in, wherein the groove has a sector angle of 0 to 180 degrees in view of Pisharodi in order to reduce friction and extend the life of the implant.

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (U.S. Patent No. 7273496) in view of Pisharodi (U.S. Patent No. 6610093) and further in view of Michelson (U.S. Publication No. 2002/0052656).

Mitchell and Pisharodi disclose the claimed invention except for the upper and lower sections having two threaded drill holes running through the ventral side to the apposition surfaces with longitudinal axes forming an angle in the range between 20-65 degrees and diverge from the inner surfaces against the apposition surfaces. Michelson teaches an intervertebral implant 800 having upper and lower members. Each member has two threaded holes passing from the interior of implant 800 through the apposition surfaces (Figures 42-46). With further reference to the figures, the holes form angles with the central axis and diverge from the inner surfaces against the apposition surfaces. The holes are for rigidly securing the implant to the vertebral segment and also to pull each of the adjacent vertebral bodies toward the implant and towards each other (Paragraph 157).

The angle which the longitudinal axes of the holes makes with the central axis is not disclosed, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the holes at an angle between 20 and 65 degrees in relation to the central axis, since it has been held that where the general

conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Furthermore, the shape of the holes is not disclosed, however, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the holes that are conically tapered towards the apposition surfaces, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. In re Dailey and Eilers, 149 USPQ 47 (1966).

It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Mitchell in view of Pisharodi with two threaded drill holes running through the ventral side to the apposition surfaces with longitudinal axes forming an angle in the range between 20-65 degrees and diverge from the inner surfaces against the apposition surfaces in view of Michelson so that the implant can be rigidly secured to the vertebral segments and also so each adjacent vertebrae can be pulled towards each other.

Claims 8-13 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (U.S. Patent No. 7273496) in view of Pisharodi (U.S. Patent No. 6610093) and further in view of Krueger et al. (U.S. Publication No. 2004/0143332).

Mitchell and Pisharodi disclose the claimed invention except for a means for keeping the ventral side areas at a fixed distance, and means for temporarily blocking mobility, where in the means is an insert with a lower end, an upper end, and a dovetail

depression on the ventral sides where the insert can be inserted and the method associated with inserting the implant. Krueger et al. teaches an articulating implant a means 210 for keeping the two sections at a fixed distance and for blocking mobility and can be attached to the ventral side areas of the implant 100. More specifically, the means has an insert 218 that has an upper surface a lower surface, and the upper and lower sections of the implant 100 have a depression 114 for receiving the implant. The insert can be dovetailed to match the depression 114 (Paragraph 130). Furthermore, the dovetail guides are tapered from the ventral side towards the dorsal side (Figure 42). In use, the insert 218 is inserted into the implant at depression 114, the implant is inserted into the intervertebral space, and the insert 218 is removed after inserting. If further positioning is required, the insert 218 can be reinserted and the implant adjusted (Paragraphs 129-134). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Mitchell in view of Pisharodi with a dovetailed shape insert and a complimentary depression in the plates to block mobility and keep the implant at a fixed height in view of Krueger et al. Using the known method and device as taught by Krueger et al. to install an implant would have been obvious to one skilled in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Yang whose telephone number is 571-272-3472. The examiner can normally be reached on 8:00am-5:30pm: Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A.Y.
10/26/2007

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER